### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	
John F. BOYLAN et al.	) Group Art Unit: 3731
Application No.: 10/764,841	) Examiner: Ryan J. Severson
Filed: January 26, 2004	) Confirmation No.: 9783
For: NITINOL ALLOY DESIGN FOR SHEATH DEPOLYABLE AND RE-SHEATHABLE VASCULAR DEVICES	Via EFS-WEB ) )

Attention: Mail Stop Appeal Brief-Patents

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

## REPLY BRIEF UNDER 37 C.F.R. § 41.41

Pursuant to 37 C.F.R. § 41.41, Appellants present this Reply to the Examiner's Answer dated October 29, 2008 ("Answer"). This Reply is timely filed within two-months of the mailing date of the Answer, December 29, 2008. A Request for Oral Hearing is concurrently filed with this Reply Brief.

### I. STATUS OF THE REJECTIONS

As set forth in the Appeal Brief filed August 26, 2008, claims 7-14 are canceled, and claims 1-6 and 15-20 are pending. Claims 1-6 and 15-20 stand rejected and are under appeal.

#### II. RESPONSE TO THE ARGUMENTS IN THE EXAMINER'S ANSWER

A. Rejection of Claims 1, 2, 4, 6 and 15-20 under 35 U.S.C. § 103(a) over Tsugita in view of Mitose

The Examiner maintains the rejection of claims 1, 2, 4, 6 and 15-20 under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 5,910,154 to Tsugita et al. ("Tsugita") in view of U.S. Patent No. 5,885,381 to Mitose et al. ("Mitose"). Answer, p. 3. Appellants maintain their position that the Examiner has failed to establish that these claims are unpatentable over Tsugita and Mitose for the reasons of record and for the additional reasons discussed below.

The key to supporting any rejection under 35 U.S.C. § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious."

M.P.E.P. § 2143. It is important to note that the prior art references relied upon in a rejection "must be considered in its entirety, i.e., as a <a href="whole">whole</a>, including portions that would lead away from the claimed invention," when such reasons are articulated by the Examiner. M.P.E.P. § 2141.02(VI). Appellants submit that the Examiner has not established a <a href="prima facie">prima facie</a> case of obviousness over Tsugita and Mitose for at least the following reasons.

The Examiner has admitted that Tsugita "does not disclose the superelastic alloy includes a ternary element." Answer at p. 3. To remedy this deficiency, the Examiner

At page 6 of the Answer, the Examiner asserts that:

Appellant argues Mitose et al. desire to achieve as high of a **loading** stress as possible and cites column 5, lines 22-32. However, at this location, Mitose et al. disclose in part 'a tensile force should be as high as possible in unloading.' Examiner can find no factual support for appellant's argument in the disclosure of Mitose et al. and therefore the argument is not persuasive.

Answer at p. 6 (emphasis added). Appellants submit that their statement regarding Mitose achieving "as high a loading stress as possible" contains a typographical error. "Loading" in this statement should read "unloading." The typographical error in Appellants statement should be apparent to the Examiner considering the parenthetical following Appellants statement correctly quotes the passage at column 5, lines 22-28 of

Mitose as stating that a tensile force should be as high as possible in <u>un</u>loading, not loading.

The Examiner further asserts at page 6 of the Answer that Appellant is using a known material (the nickel-titanium-palladium alloy of Mitose et al.) in a known product (the filter assembly of Tsugita et al.). Answer at p. 6. The Examiner concludes that the claimed invention would be obvious because "simple substitution of one known element for another (substituting the nickel-titanium alloy with the nickel-titanium-palladium alloy) to obtain predictable results is within the level of one of ordinary skill in the art." *Id.* 

To reject a claim based on this "simple substitution" rationale, the Examiner must articulate a finding that one of ordinary skill in the art could have substituted one known element for another, and the results of the substitution would have been predictable.

See M.P.E.P. § 2143(B) (emphasis added). Even if one of ordinary skill in the art could have substituted the nickel-titanium alloy of Tsugita with a nickel-titanium-palladium alloy, as asserted by the Examiner, the results of such a substitution would not have been predictable. The express teachings of Mitose support this position since they show achieving a smaller hysteresis in the opposite manner than that claimed.

Furthermore, Appellants have presented evidence, e.g. the Boylan article, showing that the results of the Examiner's proposed substitution (substituting the nickel-titanium alloy with a nickel-titanium-palladium alloy) are unexpected. Thus, the Examiner has failed to establish a prima facie case of obviousness based on this rationale.

For the reasons of record and the additional reasons discussed above,

Appellants submit that the Examiner has failed to establish a *prima facie* case of
obviousness over Tsugita and Mitose. Moreover, even if the Examiner has established

that the claimed invention is obvious, which Appellants do not concede, Appellants have present sufficient evidence, e.g., the Boylan article, to rebut any *prima facie* showing.

B. Rejection of Claims 3 and 5 under 35 U.S.C. § 103(a) over Tsugita in view of Mitose and further in view of Clark

The Examiner maintains the rejection of claims 3 and 5 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Tsugita in view of Mitose and further in view of U.S. Patent No. 5,713,853 to Clark et al. ("Clark"). Answer at p. 5. Appellants presented arguments addressing this rejection in the Appeal Brief filed August 26, 2008. The Examiner has not responded to Appellants' arguments in the Answer. Thus, Appellants maintain their position that the Examiner has failed to establish that these claims are unpatentable over Tsugita, Mitose, and Clark for the reasons already of record.

# III. CONCLUSION

For the reasons of record and the additional reasons given above, pending claims 1-6 and 15-20 are allowable. For at least these reasons, Appellants respectfully request that the Board reverse each of the Examiner's rejection.

If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: December 29, 2008

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